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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/766,530

01/29/2004

Henrich Cheng

681942-1US

2231

570

7590

08/04/2009

PANITCH SCHWARZE BELISARIO & NADEL LLP  
ONE COMMERCE SQUARE  
2005 MARKET STREET, SUITE 2200  
PHILADELPHIA, PA 19103

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

08/04/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/766,530	<b>Applicant(s)</b> CHENG, HENRICH	
	<b>Examiner</b> MICHAEL G. MENDOZA	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 23-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. The affidavit filed on 7/14/2009 under 37 CFR 1.131 has been considered but is ineffective to overcome the Cheng et al. reference.
2. The examiner agrees that the Cheng et al. reference teaches bridging a gap between within the central nervous system. However, it would have been obvious to one of ordinary skill in the art to apply the same teaching/method for bridging a gap anywhere within the nervous system including a gap between the central and peripheral nervous system. Furthermore, the patent recites that "Nerve bridges were created between the peripheral nerves and the spinal cord" (col. 1, lines 33-34).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
4. Claims 1-21, 23-27 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. 6235041 in view of Schenck et al. 4553542.
5. As to claims 1 and 2, Cheng et al. teaches a method of functionally connecting a portion of the peripheral nervous system of a vertebrate to a portion of the central or peripheral nervous system of the vertebrate, comprising the steps of bringing a portion of the peripheral nervous system and the portion of the central or peripheral nervous system close to each other, applying to the gap between the two portions a fibrin glue

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mixture comprising a growth factor, fibrinogen, aprotinin and divalent calcium ions so that the fibrin glue mixture (col. 6, lines 1-16) is simultaneously in contact with the two portions, and forming an attachment between the portion of the peripheral nervous system and the portion of the central or peripheral nervous system of the vertebrate (col. 1, lines 27-34). It should be not that Cheng et al. fails to teach suturing or anastomosing the two portions of the nervous system to be connected.

6. Schenck et al. teach a method for connecting portions of a nerve comprising suturing portions of a nerve together (col. 15, lines 32-43). It would have been obvious to one having ordinary skill in the art at the time the invention was made to suture two portions of the nervous system together of Cheng et al. in view of Schenck et al. for forming a strong connection to allow the glue of Cheng et al. to set and form a permanent bond.

7. As to claims 2-9, 12-19, and 23-26, Cheng/Schenck teaches the method of claim 1, wherein the growth factor is selected from the group consisting of a glial cell line-derived neurotrophic factor, transforming growth factor-beta, fibroblast growth factor, platelet-derived growth factor, and epidermal growth factor, vascular endothelial growth factor, and neurotrophin (col. 5, lines 66-67); wherein the fibroblast growth factor is acidic fibroblast growth factor; wherein the divalent calcium ions are provided by the addition of calcium chloride or calcium carbonate; wherein the fibrin glue mixture is acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, line 1-16); the step of introducing a tissue graft to the gap between the portion of the

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peripheral nervous system and the portion of the central nervous system; wherein tissue graft is a sural or intercostal nerve of said vertebrate (col. 7, lines 55-60).

8. As to claim 10, Cheng et al. teaches a vial B with 1 ml of aprotinin solution with 1000 KIU bovine lung aprotinin. This solution is mixed with vial D containing 2.5 ml of calcium chloride solution. Bringing the total volume of the solution of B + D to 3.5 ml. Added to the solution of C + D, dry fibrinogen between 115-232 mg in a vial A and dry thrombin between 4.9-11.1 mg in a vial C, to bring the total volume above 3.5 ml. For ease of calculation the examiner will use the solution volume of 3.5 ml. The solution of 3.5 ml with a total of 1000 KIU of aprotinin in the solution would equate to approximately 286 KIU/ml of solution. Therefor Cheng et al. reads on the limitation of the fibrin glue mixture comprises 0.0001-1000 mg/ml of fibroblast growth factor, 10-1000 mg/ml of fibrinogen, 10-500. KIU/ml of aprotinin and 1-100 mM of calcium chloride

9. As to claim 12-21, 25, and 26, the method as taught by Cheng/Schenck teaches connecting the nervous system of the vertebrate and be used to connect any portion of the nervous system of the vertebrate including the cervical root to the spinal cord.

10. As to claims 10, 11, 20, and 21, it has been held to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. *Ex parte Pfeiffer*, 1962 C.C. 408. (1961).

11. As to claim 11, Cheng et al. teach a mixture comprising acidic fibroblast growth factor, fibrinogen, aprotinin and calcium chloride (col. 6, lines 1-16). It should be noted that fails to specifically disclose 1 mg/ml of fibroblast growth factor, 100 mg/ml of

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fibrinogen, 200 KIU/ml of aprotinin, and 8mM of calcium chloride. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed amounts, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/M. G. M./  
Examiner, Art Unit 3734

/Todd E Manahan/  
Supervisory Patent Examiner, Art Unit 3734